UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

CASSANDRA SUTTON, et al.,	)	
	)	
Plaintiffs,	)	
	)	**No. 4:20-cv-364 SNLJ**
vs.	)	
	)	
ETHICON, INC., et al.,	)	
	)	
Defendants.	)	

MEMORANDUM AND ORDER

This matter was originally filed on a short-form complaint in *In re: Ethicon, Inc., Pelvic Repair System Products Liability Litigation*, MDL No. 2327 (S.D. W. Va.), on June 27, 2013. The case was transferred to this Court on March 9, 2020 and assigned to the undersigned on July 16, 2020. In late 2019, defendants Johnson & Johnson and Ethicon, Inc. moved for partial summary judgment [#56] and to exclude the opinions and testimony of plaintiff's expert, Dr. Bruce Rosenzweig [#54]. Plaintiffs oppose the motions.

I. Background

As explained further below, Plaintiff Cassandra Sutton alleges injuries caused by the implantation of pelvic mesh devices for treatment of stress urinary incontinence including TVT Secur ("TVT-S"), TVTAbbrevo ("TVT-A"), TVT Exact ("TVT-E"), and TVT. On July 15, 2010, Ms. Sutton underwent implantation of Ethicon's product TVT-S. Dr. Luis Mertins in Crystal City, Missouri performed the operation. During this same

procedure, Dr. Mertins also implanted an Elevate System with IntePro Lite, which was manufactured by American Medical Systems, Inc. ("AMS").

On June 27, 2013, plaintiff Sutton and her husband Robert Sutton directly filed suit in the Ethicon Pelvic Mesh MDL, naming both Ethicon and AMS as defendants. Plaintiffs alleged that a defect in Ms. Sutton's Ethicon-manufactured TVT-S caused her various injuries.

On August 15, 2013, just after filing suit against Ethicon, Ms. Sutton underwent implantation of another Ethicon product, TVT-A, for treatment of recurrent stress urinary incontinence performed by Dr. Mertins in Crystal City, Missouri. During this same operation, Dr. Mertins removed Ms. Sutton's TVT-S.

On March 14, 2014, with her complaint against Ethicon still in the MDL, Ms. Sutton underwent implantation of another Ethicon product, the TVT-E, for treatment of stress urinary incontinence. Dr. James Lovinggood implanted her TVT-E in St. Louis, Missouri. During that same operation, Dr. Lovinggood excised Ms. Sutton's TVT-A.

On March 28, 2014, with her complaint against Ethicon still pending in the MDL, Ms. Sutton underwent implantation of another Ethicon product, TVT, for treatment of recurrent stress urinary incontinence. Dr. Lovinggood implanted Ms. Sutton's TVT and removed Ms. Sutton's previous TVT-E.

Plaintiff claims that her implanted Ethicon products have caused her urinary leakage, pelvic pain, vaginal discharge and infections, dyspareunia, exposure, and urinary frequency. Plaintiffs filed an Amended Complaint in the MDL on June 17, 2015. In their Amended Short Form Complaint, Plaintiffs assert the following claims against both Ethicon and AMS: negligence (Count 1); strict liability – manufacturing defect

(Count 2); strict liability – failure to warn (Count 3); strict liability – defective product (Count 4); strict liability – design defect (Count 5); common law fraud (Count 6); fraudulent concealment (Count 7); constructive fraud (Count 8); negligent misrepresentation (Count 9); negligent infliction of emotional distress (Count 10); breach of express warranty (Count 11); breach of implied warranty (Count 12); violation of consumer protection laws (Count 13); gross negligence (Count 14); unjust enrichment (Count 15); loss of consortium (Count 16); punitive damages (Count 17); and discovery ruling and tolling (Count 18). Plaintiff has since settled with defendant AMS.

Plaintiff has disclosed Dr. Bruce Rosenzweig as her expert witness. Defendants argue that Dr. Rosenzweig testified that the first implant, the TVT-S, was the sole cause of Ms. Sutton's alleged injuries, and that, as a result, summary judgment should be granted in their favor on several claims.

II. Motion for Partial Summary Judgment

Pursuant to Federal Rule of Civil Procedure 56(c), a district court may grant a motion for summary judgment if all of the information before the court demonstrates that "there is no genuine issue as to material fact and the moving party is entitled to judgment as a matter of law." *Poller v. Columbia Broadcasting System, Inc.*, 368 U.S. 464, 467 (1962). The burden is on the moving party. *City of Mt. Pleasant, Iowa v. Assoc. Elec. Co-op., Inc.*, 838 F.2d 268, 273 (8th Cir. 1988). After the moving party discharges this burden, the nonmoving party must do more than show that there is some doubt as to the facts. *Matsushita Elec. Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). Instead, the nonmoving party bears the burden of setting forth specific facts showing that there is sufficient evidence in its favor to allow a jury to return a verdict for it. *Anderson*

v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986); *Celotex Corp. v. Catrett*, 477 U.S. 317, 324 (1986).

In ruling on a motion for summary judgment, the court must review the facts in a light most favorable to the party opposing the motion and give that party the benefit of any inferences that logically can be drawn from those facts. *Buller v. Buechler*, 706 F.2d 844, 846 (8th Cir. 1983). The court is required to resolve all conflicts of evidence in favor of the nonmoving party. *Robert Johnson Grain Co. v. Chem. Interchange Co.*, 541 F.2d 207, 210 (8th Cir. 1976).

The parties agree that Missouri law applies.

Defendants seek summary judgment on claims to the extent they are based on plaintiff's alleged injuries having been caused by defects in her TVT-A, TVT-E, and/or TVT implants. Defendants also contend that this Court should dismiss, with prejudice, plaintiffs' claims for negligence (to the extent based on negligent manufacturing defect) (Count 1), strict liability – manufacturing defect (Count 2); strict liability – defective product (Count 4); common law fraud (Count 6); fraudulent concealment (Count 7); constructive fraud (Count 8); negligent misrepresentation (Count 9); negligent infliction of emotional distress (to the extent based on negligent manufacturing defect) (Count 10); breach of express warranty (Count 11); breach of implied warranty (Count 12); violation of consumer protection laws (Count 13); gross negligence (Count 14); and unjust enrichment (Count 15).

Plaintiffs filed a response memorandum opposing summary judgment, but they do not address defendants' arguments regarding Counts 1, 2, 4, 6, 7, 8, 9, 11, 12, 13, 14, or

15, tacitly conceding that those counts should be dismissed. *See O'Shaughnessy v. Cypress Media, L.L.C.*, 208 F. Supp. 3d 1064, 1074 (W.D. Mo. 2016). As a result, summary judgment will be granted to defendants on those Counts. Only Counts 3 (strict liability – failure to warn), 5 (strict liability – design defect), and 10 (negligent infliction of emotional distress) remain for discussion.

Defendants contend that plaintiffs' claims arise from the allegation that defects in, or misrepresentations regarding, Ethicon mesh products caused Ms. Sutton's personal injuries. Under Missouri law, "expert testimony is necessary and, therefore required," when "a fact at issue is so technical or complex that no fact finder could resolve the issue without expert testimony." *Stone v. Mo. Dep't of Health & Senior Servs.*, 350 S.W.3d 14, 21 (Mo. *banc* 2011) (internal quotation omitted). Expert testimony is so-required, for example, "to establish causation when there is a sophisticated injury that involves a highly scientific technique for diagnosis." *Id.* Defendants' primary argument is that plaintiff has failed to disclose any expert testimony establishing that a defect in Ethicon's TVT-A, TVT-E, and TVT products proximately caused Ms. Sutton's alleged injuries. Rather, defendants say, plaintiffs' expert testified only that the first-implanted device, the TVT-S, caused plaintiff's problems. As a result, defendants seek summary judgment on all of plaintiffs' claims to the extent they are based on injuries caused by defects in her TVT-A, TVT-E, or TVT devices. Notably, however, Count 3 is for strict liability – failure to warn, and although in such a claim "plaintiff must show a product was unreasonably dangerous, Missouri law does not hold that a finding of a product defect [is] a necessary predicate to a failure to warn action." *Chole v. Boston Sci. Corp.*, 4:19-

CV-02976 JAR, 2020 WL 1853266, at *5 (E.D. Mo. Apr. 13, 2020) (quoting *Moore v. Ford Motor Co.*, 332 S.W.3d 749, 757 (Mo. *banc* 2011)).

Plaintiffs do not contest that expert testimony is required to prove her remaining products claim (Count 5 for strict liability – design defect), but she insists that her expert provides the required testimony.

Both plaintiff and defendants rely on essentially the same deposition testimony, which is as follows:

> Q. Do you intend to testify at trial in this case that the TVT Abbrevo caused injury to Ms. Sutton?
>
> A. No. The TVT-Secur is the device that set up the chronic foreign body reaction, chronic inflammatory reaction, scarification, tissue damage that led to the continuing issues that she had, even with addition of the Abbrevo, the Exact, and the TVT Retropubic.
>
> Q. Okay. So do you believe that the TVT Abbrevo caused a chronic inflammatory reaction, foreign body response in Ms. Sutton?
>
> A. The TVT Abbrevo further continued the chronic foreign body reaction, chronic inflammatory reaction that was initiated by the TVT-Secur.
>
> Q. Okay. Is it your opinion that a defect in the TVT Abbrevo caused injury to Ms. Sutton?
>
> A. No.
>
> Q. Is it your opinion that a defect in the TVT Exact caused injury to Ms. Sutton?
>
> A. No.
>
> Q. Is it your opinion that a defect in the TVT caused injury to Ms. Sutton?

A. No.

Q. Do you believe that all of Ms. Sutton's alleged injuries in this case are attributable to the TVT-Secur?

A. Correct.

Q. And solely the TVT-Secur?

A. Correct.

Defendants look to the second half of this excerpt and summarize that Rosenzweig testified there is no causal relationship between plaintiff's alleged injuries and her last three implanted devices (the TVT-A, TVT-E, and TVT). Plaintiffs, relying on the first half of the quoted testimony, maintain that Dr. Rosenzweig did testify that the three subsequent mesh devices continued the chronic foreign body reaction and chronic inflammatory reaction that was initiated by the TVT-S. But he denied that the TVT-A had "caused injury" to plaintiff, and then he went on to say the TVT-A, TVT-E, and TVT did not have defects.

Plaintiffs point out that Dr. Mertins—who implanted the first devices—testified that the TVT-S and the TVT-A had "failed" in treating Ms. Sutton's stress urinary incontinence. That testimony, however, does not speak to whether a defect in the product caused plaintiff's harm.

This Court agrees that plaintiff has not produced expert testimony supporting that a defect in the three subsequent devices had caused plaintiff's injury. In fact, Dr. Rosenzweig's testimony is just the opposite. This Court will grant the motion for

summary judgment on Count 5 to the extent it is based on plaintiff's alleged injuries having been caused by defects in her TVT-A, TVT-E, and/or TVT.

The remaining count then is Count 10 for negligent infliction of emotional distress. Defendants argue that the claim requires a plaintiff to prove, inter alia, that she suffered "medically diagnosable" "emotional distress or mental injury…of sufficient severity to be medically significant." *Henson v. Greyhound Lines, Inc*., 257 S.W.3d 627, 629 (Mo. App. W.D. 2008). Furthermore, "under Missouri law, emotional distress injuries are considered 'sophisticated' ones, outside the realm of lay understanding," thus "those injuries must be established through expert testimony as well." *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1210 (8th Cir. 2000). Plaintiffs' expert does not identify any mental injuries caused by or related to plaintiff's Ethicon implants. In her response memorandum, plaintiff states only that her amended petition, deposition, and plaintiff fact sheet "detail at length the loses and harms suffered." [#59 at 3.] That does not suffice, and it does not constitute expert testimony as required by Missouri law. Summary judgment will be granted to defendants as to Count 10.

III. Motion to limit the case-specific opinions and testimony of Dr. Rosenzweig

Federal Rule of Evidence 702, amended after *Daubert v. Merrell Dow Pharmaceuticals, Inc*., 509 U.S. 579 (1993), provides the standard for the admission of expert testimony:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the

> testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

The Eighth Circuit provides a three-part test based on that rule to determine the admissibility of expert testimony:

> First, evidence based on scientific, technical, or other specialized knowledge must be useful to the finder of fact in deciding the ultimate issue of fact. This is the basic rule of relevancy. Second, the proposed witness must be qualified to assist the finder of fact. Third, the proposed evidence must be reliable or trustworthy in an evidentiary sense, so that, if the finder of fact accepts it as true, it provides the assistance the finder of fact requires.

Lauzon v. Senco Prod. Inc., 270 F.3d 681, 686 (8th Cir. 2001) (internal quotations and citations omitted). "The rules for the admissibility of expert testimony favor admission over exclusion." *Dorgan v. Ethicon, Inc*., 4:20-00529-CV-RK, 2020 WL 5367062, at *1 (W.D. Mo. Sept. 8, 2020) (citing *id.*).

Defendants do not appear to attack Dr. Rosenzweig's credentials. Instead, they seek to preclude Dr. Rosenzweig from offering the following expert testimony and opinions at trial in this case: (1) opinions regarding the TVT-A, TVT-E and TVT devices implanted in Ms. Sutton, including any opinion that she has been injured by any alleged defect in one or more of these devices; (2) opinions regarding alternative procedures/designs; (3) the opinion that Ethicon's allegedly inadequate warnings prevented Ms. Sutton's implanting physicians from providing proper informed consent for her implant procedures; (4) opinions regarding corporate knowledge and state-of-mind, as well as opinions containing legal conclusions and terms of art; (5) opinions regarding complications not experienced by Ms. Sutton, including the

risk of experiencing such complications in the future; and (6) Dr. Rosenzweig's opinion that Ms. Sutton has experienced chronic pelvic and/or vaginal pain and dyspareunia caused by alleged defects in the TVT-S.

Plaintiff did not respond to defendants' arguments regarding topics 1, 4, or 5. Defendants' motion will thus be granted on those matters as unopposed.

The remaining topics are discussed in turn below.

A. Safer alternative treatments and designs

Dr. Rosenzweig opines that "there were feasible, reasonably safe alternatives" to Ethicon's TVT-S that would have "eliminated the risk of the injuries suffered by Ms. Sutton[,]" including the following: the use of sutures in a Burch procedure; autologous fascia sling; an allograft sling, such as the Repliform; and a sling made from PVDF or Ultrapro. Defendants argue that opinions regarding non-mesh surgeries and treatments for stress urinary incontinence should be excluded because they are not helpful to the jury. It is clear that treatment alternatives are not relevant to the design of the device; "[w]hile such an opinion might be relevant in a malpractice suit against a doctor, it is irrelevant in a suit against the product manufacturer." *Talley v. Danek Med., Inc.*, 179 F.3d 154, 162 (4th Cir. 1999). Plaintiffs say Dr. Rosenzweig's testimony is relevant to the question of negligence under Missouri law because the jury needs to know whether Ethicon brought its mesh product into a market that had no other options for the treatment of injuries like plaintiff's. But the MDL court held that "alternative procedures/surgeries do not inform the issue of whether an alternative design for a product exists." *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2327, 2017 WL 1264620, at

*3 (S.D.W. Va. Mar. 29, 2017); *accord Mullins v. Johnson & Johnson*, 236 F. Supp. 3d 940, 942 (S.D.W. Va. 2017) ("I am convinced that an alternative, feasible design must be examined in the context of products—not surgeries or procedures.").

> This is so, because whether an alternative procedure could have been performed without the use of the [device] does nothing to inform the jury on the issue of an alternative, feasible design for the [device]. The choice of a surgery over a device is a matter of medical judgment of treating doctors, not whether there is a safer alternative design for the product.

Willet v. Johnson & Johnson, 112CV00034JAJRAW, 2020 WL 2988299, at *8, --- F. Supp. 3d --- (S.D. Iowa June 3, 2020) (internal quotation to *Mullins*, 236 F. Supp. 3d at 943, omitted).[1]

As for Dr. Rosenzweig's "alternatives" that actually go to the design of the device, defendants argue that his opinions favoring a sling constructed of Ultrapro or PVDF mesh have no scientific basis. Plaintiffs devote very little time to this matter in their memorandum, as they mainly appear to address the relevance of alternative treatment. Plaintiffs' only defense of Dr. Rosenzweig's design opinions appears to be invocation of his review of "hundreds of thousands of pages of Ethicon internal documents, Ethicon deposition testimony and peer-reviewed literature that is cited in his reports and included in his reliance materials which support his opinions and the bases thereof." [#58 at 5.]

[1] *But see, e.g., Herrera-Nevarez by Springer v. Ethicon, Inc.*, 12 C 2404, 2017 WL 3381718, at *7 (N.D. Ill. Aug. 6, 2017), in which the court allowed an expert to testify as to other procedures as alternatives to TVT devices because "Under Illinois product liability law, a plaintiff may attempt to prove that the design of a product is unreasonably dangerous using the "risk-utility" test. *See also Wiltgen v. Ethicon, Inc*., 12-CV-2400, 2017 WL 4467455, at *4 (N.D. Ill. Oct. 6, 2017) ("The availability of other safe and effective procedures (including surgical procedures) to treat the same condition is relevant and admissible to show the utility of a product.").

Then plaintiffs cite to Rosenzweig's General Report (which was not filed with the briefing on the present motion) without further explication.

Returning to the defendants' argument, defendants say Dr. Rosenzweig's design opinions are unconnected to any reliable methodology and unsupported by medical literature. First, defendants argue that the "opinion that a 'sling with less polypropylene such as Ultrapro' is a safer alternative design than the TVT-O is unreliable and should be excluded because this proposed alternative was not feasible." [#55 at 8.] This argument is perplexing because Ms. Sutton was implanted only with TVT-S, TVT-A, TVT-E, and TVT products, and this Court has already narrowed this case to the TVT-S alone. Although it is unclear whether this argument is thus even viable, it appears that the MDL Court has since rejected challenges to the reliability of Dr. Rosenzweig's testimony regarding Ultrapro mesh as an alternative design. *In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL 2327, 2020 WL 1061091, at *4 (S.D.W. Va. Feb. 13, 2020).

Second, defendants contend that scientific studies refute Dr. Rosenzweig's opinion that plaintiff would not have suffered injury if she had been implanted with a sling made from PVDF. It is unclear from the briefing and material submitted whether such a sling is an alternative treatment or an alternative design. Defendants' point with respect to an Ultrapro sling, to the extent it is relevant here, suffers from the same opacity. Without more information, this Court is unable "to draw the fine line between reliable and unreliable expert testimony." *Id.* Accordingly, the motion on both points will be denied without prejudice. It may be that, as was discussed in the MDL, "the critical gatekeeping

function permitting or denying expert testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination." *Id.*

B. Opinions regarding informed consent

Next defendants assert that Rosenzweig should not be permitted to opine that Ethicon's allegedly inadequate warnings prevented Ms. Sutton's implanting physicians from providing proper informed consent for her implant procedures. Defendants argue that allowing such testimony effectively opines as to the physicians' personal knowledge at the time of plaintiff's surgeries, which is not helpful. *See In re: Ethicon, Inc.*, No. 2:12-md-2327, 2016 WL 4493457, at *3 (S.D. W. Va. Aug. 25, 2016) (excluding testimony "on what 'all physicians' know or should know or what 'all physicians' rely on in making informed decisions). This Court agrees that Dr. Rosenzweig may not testify regarding the knowledge of other physicians, and also that the adequacy of the informed consent process is not at issue in this case. As plaintiffs point out, however, it is relevant whether the warnings provided by Ethicon to the implanting physicians were adequate. And, as the MDL Court stated in a related expert motion, "an expert who is a urogynecologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *In re: Ethicon, Inc.*, 2:12-MD-02327, 2016 WL 4536885, at *2 (S.D. W. Va. Aug. 30, 2016).

C. Opinions regarding chronic vaginal/pelvic pain and dyspareunia

Finally, defendants argue that Dr. Rosenzweig should not be permitted to opine that plaintiff has suffered chronic pain and dyspareunia caused by defects in the TVT-S because Rosenzweig arrived at that conclusion via a flawed differential diagnosis.

Defendants argue these opinions are unreliable because they are not grounded in the evidence.

"A differential diagnosis determines all of the possible causes for the patient's symptoms and then eliminates each of these potential causes until reaching one that cannot be ruled out, or deduces which of those that cannot be excluded is the most likely." *Johnson v. Mead Johnson & Co., LLC*, 754 F.3d 557, 560 (8th Cir. 2014). "Differential diagnoses are generally admissible," but "should be excluded if they are scientifically invalid." *Junk v. Terminix Int'l Co.*, 628 F.3d 439, 449 (8th Cir. 2010).

Dr. Rosenzweig arrived at his conclusion by reviewing medical records. Defendants point out that he apparently arrived at this opinion despite there being only one recorded complaint of pelvic pain in December 2013 and no further complaints of pain or dyspareunia since the TVT-S was implanted. He also admits that the Elevate mesh—with which plaintiff was implanted at the same time—can degrade and cause pain, scarring, and dyspareunia. But Rosenzweig testified he was able to rule out the Elevate mesh as a cause of complaints because operative reports from surgeries after the TVT-S document findings of weak vaginal tissue and scarring. This is an appropriate subject for cross-examination, not a reason to exclude the testimony. Finally, although defendants complain that Dr. Rosenzweig relied upon information gleaned from Ms. Sutton's Plaintiff Fact Sheet ("PFS"), such a document was a routine and required part of discovery in this case. To the extent defendants take issue with PFS statements, they may cross-examine plaintiff and her expert. *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 702 (S.D.W. Va. 2014). Although it is a close case, this Court finds that the differential diagnosis is sufficiently reliable.

IV. Conclusion

Summary judgment will be granted to defendants on Counts 1, 2, 4, 6, 7, 8, 9, 10, 11, 12, 13, 14, and 15. Summary judgment will also be granted to defendants on Count 5 to the extent it is based on injuries having been caused by defects in plaintiff's TVT-A, TVT-E, and/or TVT. Dr. Rosenzweig's opinions will be partially excluded as explained herein.

Remaining claims in this matter are thus Count 5 as it pertains to plaintiff's TVT-S device and Count 3.

Accordingly,

IT IS HEREBY ORDERED that defendants' motion for summary judgment [#56] is GRANTED in part and DENIED in part.

IT IS FURTHER ORDERED that summary judgment is GRANTED as to Counts 1, 2, 4, 6, 7, 8, 9, 10, 11, 12, 13, 14, and 15, and DENIED as to Count 3.

IT IS FURTHER ORDERED that summary judgment is GRANTED as to Count 5, to the extent it pertains to injuries caused by plaintiff's TVT-A, TVT-E, and/or TVT.

IT IS FURTHER ORDERED that defendants' motion to limit the testimony of Dr. Bruce Rosenzweig [#54] is GRANTED in part and DENIED in part.

IT IS FINALLY ORDERED that the parties shall submit a joint proposed case management order by October 13, 2020.

Dated this 29th day of September, 2020.

STEPHEN N. LIMBAUGH, JR.
SENIOR UNITED STATES DISTRICT JUDGE